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Sterile packaged ready for filling glass cartridges

Cartouches en verre préremplissables sous emballage stérile

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.*

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In the last few years, following the more and more urgent request for ready for filling containers, packaging manufacturers managed to offer to the pharmaceutical industry containers already washed and sterilized. This category of products was born about 30 years ago with the appearance on the market of ready for filling syringes.

Only recently, the sterilized sub-assembled ready for filling syringes have been standardized by ISO 11040-4 and ISO 11040-7, including the corresponding packaging system. These two International Standards define the performance requirements of the glass syringes and the related test methods, as well as the ready for filling packaging system for these syringes, also including the test methods.

ISO 13926-1 specifies the design, dimensions, materials, performance and test methods for glass cylinders used with pen-injectors for medical use.

Due to the increasing market presence of syringes ready for filling and the associated advantages of this product for the pharmaceutical industry, the suppliers of packaging materials have started to develop such systems of this type for cartridges.

The availability of two packaging configurations makes ready for filling glass cartridges suitable for use both in clinical trials and in mass production. Nest and tub configuration has been conceived to be used usually with automated filling machines, while tray configuration is usually suitable for small batches filled manually or by means of semi-automated filling machines.

This duality of packaging configurations calls for a standardization of the production processes, materials quality and analytical methods when launching these products on the market, in order to avoid conceiving too highly customized processes.

Sterile packaged ready for filling glass cartridges

1 Scope

This document specifies the characteristics of sterile and ready for filling empty glass cartridges for injectable preparations, including the minimum requirements of materials, packaging systems and analytical test methods.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 720, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11138 (all parts), *Sterilization of health care products — Biological indicators*

ISO 11140 (all parts), *Sterilization of health care products — Chemical indicators*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11608-3:2012, *Needle-based injection systems for medical use — Requirements and test methods — Part 3: Finished containers*

ISO 13926-1:2018, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
cap
component which attaches the *disc* (3.3) to the cartridge

[SOURCE: ISO 11608-3:2012, 3.1]

3.2
customer
business entity which purchases sterile ready for filling cartridges and conducts further processing or filling as appropriate